



## Complete Summary

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### **GUIDELINE TITLE**

Inhaler devices for routine treatment of chronic asthma in older children (aged 5–15 years).

### **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Clinical Excellence (NICE). Inhaler devices for routine treatment of chronic asthma in older children (aged 5-15 years). London (UK): National Institute for Clinical Excellence (NICE); 2002 Mar. 19 p. (Technology appraisal guidance; no. 38).

### **GUIDELINE STATUS**

This is the current release of the guideline.

April 2005: "Having re-run the search strategy from the original assessment report the Institute found no relevant additions to the evidence base that would have a material effect on the guidance. Consequently NICE proposed that the original guidance become static. In May 2005, a decision was made to make it a static guideline. See Review Proposal and Review Decision available at the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

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## **SCOPE**

### **DISEASE/CONDITION(S)**

Chronic asthma

### **GUIDELINE CATEGORY**

Management  
Prevention  
Technology Assessment  
Treatment

## **CLINICAL SPECIALTY**

Allergy and Immunology  
Family Practice  
Internal Medicine  
Nursing  
Pediatrics  
Pharmacology  
Preventive Medicine  
Pulmonary Medicine

## **INTENDED USERS**

Nurses  
Physician Assistants  
Physicians  
Respiratory Care Practitioners

## **GUIDELINE OBJECTIVE(S)**

To examine the clinical and cost effectiveness of hand held inhalers to deliver medication for the routine management of chronic asthma in children aged between five and fifteen years

## **TARGET POPULATION**

Children aged between five and fifteen years

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Hand held inhalers (with and without spacers, as appropriate), including

- Manual pressurised metered dose inhalers (pMDIs) pressurised with either chlorofluorocarbon (CFC) or hydrofluoroalkane (HFA) propellants
- Breath-actuated metered dose inhalers
- Breath-actuated dry powder inhalers (DPIs)

## **MAJOR OUTCOMES CONSIDERED**

- Clinical effectiveness
  - Lung function
  - Symptoms
  - Ease of use
  - Preference
  - Compliance
- Cost effectiveness

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases  
Searches of Unpublished Data

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC):** The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (SchARR), University of Sheffield. (See the "Availability of Companion Documents" field.)

#### Clinical Effectiveness

##### **Search Strategy**

The search aimed to identify all papers relating to childhood asthma inhalers and outcomes previously addressed in the systematic review by Brocklebank et al.\* and published subsequent to publication of that review. The search also aimed to identify all papers that addressed childhood asthma inhalers (e.g. comparisons between different powder devices) or outcomes (e.g. patient preference/compliance, quality of life, unwanted effects, etc.) not covered in Brocklebank et al's review. An update of the Brocklebank et al. search on *in vitro* studies was also undertaken. All literature searches were conducted between April-July 2001.

\* Brocklebank D, Ram F, Wright J, Barry P, Cates C, Davies L, Douglas G, Muers M, Smith D, White J. Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature. *Health Technol Assess.* 2001;5(26):1-149.

##### *Sources Searched*

Fifteen electronic bibliographic databases were searched, covering biomedical, science, social science, health economic and grey literature (including current research). A list of databases is provided in Appendix 2 of the Assessment Report (see "Availability of Companion Documents" field).

In addition, the reference lists of the Brocklebank et al. review and other relevant articles were checked. Various health services research related resources were consulted via the Internet. These included health economics and Health Technology Assessment (HTA) organisations, guideline producing agencies, generic research and trials registers, and specialist asthma sites. A list of these additional sources is given in Appendix 3 of the Assessment Report (see "Availability of Companion Documents" field).

## *Search Terms*

A combination of free-text and thesaurus terms were used. Asthma search terms were combined with generic terms regarding asthma inhalers (e.g., administration, inhalation; aerosols, powders, meter(ed) dose(s), mdi(s), pmdi(s), etc.), and limited to children. Searches were also conducted on named inhalers and spacers (e.g., Maxivent, Spacehaler, Accuhaler, etc.). Copies of the search strategies used in the major databases are included in Appendix 4 of the Assessment Report (see "Availability of Companion Documents" field).

## *Search Restrictions*

Where possible (e.g., in the smaller databases), searches were not restricted by publication type or study design. However, methodological filters aimed at identifying guidelines, systematic reviews, clinical trials, economic evaluations, unwanted effects, compliance, and quality of life studies, were used in Medline (refer to Appendix 4 of the Assessment Report [see "Availability of Companion Documents" field] for details of the filters used). Searches for reviews, guidelines and clinical trials, were limited to 1998 onwards, as earlier studies had already been identified by the Brocklebank et al. review. No language restrictions were used.

## **Inclusion and Exclusion Criteria**

### *Inclusion Criteria*

Subjects: human patients aged between five and fifteen years with chronic asthma or experiencing a mild to moderate exacerbation (increased symptoms and reduced lung function requiring usual treatment delivery but at an increased frequency and/or dosage, not requiring emergency treatment or addition of oral steroids). For searches for "in vitro" evidence, the inclusion criteria omit "subjects."

Intervention: use of any one inhaler device to deliver bronchodilators (short and long acting beta2 –agonists, other adrenoceptor agonists, antimuscarinic bronchodilators), corticosteroids (beclometasone dipropionate, budesonide and fluticasone propionate), cromoglycate, nedocromil, or combination therapy, for the routine management of chronic asthma. This includes any inhaler devices delivering drugs not licensed for the United Kingdom (UK) but included within the categories defined above (but such drug/device combinations will be specifically identified in the review).

Inhaler devices to include:

- Pressurised metered dose aerosols, using either chlorofluorocarbon (CFC) or hydrofluoroalkane (HFA) propellant, with or without a spacer (all sizes)
- Breath actuated metered dose aerosols, using either CFC or HFA propellant
- Breath actuated dry powder devices

Comparators: Alternative inhaler devices from the list above, **but delivering the same form of medication, by generic drug, not by drug type, and at the equivalent dose level.**

#### *Exclusion Criteria*

Interventions: Any interventions on drug efficacy in isolation from device used to deliver it.

Language: Any papers not available in the English language (as a rapid review, this review is subject to a very short time scale that precludes time for translation).

Time: No date limits will be imposed.

Studies available only as abstracts will also be excluded.

## **NUMBER OF SOURCE DOCUMENTS**

### **Clinical Effectiveness**

Fourteen randomised controlled studies were identified that looked at the clinical effectiveness of inhaler devices for delivering beta2-agonists and a further seven delivering corticosteroids and one delivering cromoglycate. Seven randomised controlled trials examined the impact on clinical effectiveness of using a non chlorofluorocarbon (CFC) propellant in place of a CFC one in metered dose inhalers, both pressurised and breath activated, although only one study considered the latter type. A further 30 studies of varying quality, from ten randomised controlled trials to non-controlled studies, were identified that looked at impact of use by, and preference for, inhaler type, and adherence in children.

### **Cost Effectiveness**

No robust cost-effectiveness or utility studies examining use of inhalers in children aged 5 to 15 years with asthma were identified by the systematic review.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

**Note from the National Guideline Clearinghouse (NGC):** The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (SchARR), University of Sheffield. (See the "Availability of Companion Documents" field.)

### **Clinical Effectiveness**

#### **Data Extraction Strategy**

All abstracts, and titles for those articles for which abstracts were not available, were double read and consensus reached on which papers should be acquired for further consideration of the evidence based upon the full text of the article. All papers were read and appraised by two reviewers who extracted relevant information from the paper for this review directly onto an extraction/ evidence table. One reviewer worked with the clinical effectiveness literature and the second with the compliance/preference literature. Quality assurance was monitored by the double extraction of the first three, and a random selection of subsequent papers, by a third reviewer and comparison of the material extracted for content and accuracy.

#### **Quality Assessment Strategy**

Included papers were assessed according to the accepted hierarchy of evidence, whereby meta-analyses of randomised controlled trials are taken to be the most authoritative forms of evidence, with uncontrolled observational studies the least authoritative.

- Any randomised controlled trials were assessed with respect to randomisation procedures, blinding, handling of withdrawals and dropouts, using Jadad's scoring system.
- Non-randomised studies using quantitative data, such as case-control, cohort, case series, and case reports have been assessed with respect to validity using guidelines from the Centre for Health Evidence based upon the Users Guides to Evidence-Based Medicine.
- Qualitative evidence has been assessed using the Critical Appraisal Skills Programme (CASP) checklist for qualitative research.

In most instances, use of data from non-randomised studies has only been considered in cases where there has been insufficient evidence from good quality randomised controlled trials. This is the case for issues of ease of use, preference, compliance, and resource use. Qualitative evidence has specifically been included for issues on preference.

- The quality of the economic literature has been assessed according to the "Guidelines for authors and peer reviewers of economic submissions" to the British Medical Journal (BMJ).

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

### **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

#### **Considerations**

Technology appraisal recommendations are based on a review of clinical and economic evidence.

#### **Technology Appraisal Process**

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

#### **Who is on the Appraisal Committee?**

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

An economic analysis considering differences in overall costs between devices found that only small improvements in asthma outcomes were needed for a device to be considered cost-effective compared with the cheapest available alternative for the delivery of the same drug at the same dose. Consequently if, after taking account of the factors specified in the "Major Recommendations" field, a clinician considers that a particular device would be more likely to achieve good asthma control in a particular child than cheaper ones available, then that device should be chosen.

See Section 4 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carers groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carers groups were also invited to comment on the ACD.

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**



1. It is recommended that in addition to therapeutic need (including chosen drug and dose), the following factors be taken into account when choosing inhaler devices for individual children with chronic asthma:
  - The ability of the child to develop and maintain an effective technique with the specific device
  - The suitability of a device for the child's and carer's lifestyles, considering factors such as portability and convenience
  - The child's preference for and willingness to use a particular device.
2. The general recommendations in section 1 above should be taken into account when considering the following specific guidance:
  - A press-and-breathe pressurised metered dose inhaler (pMDI) and suitable spacer device is recommended as the first-line choice for the delivery of inhaled corticosteroids as part of regular planned daily therapy, with the aim of maximising benefits of preventive therapy in attaining good asthma control, and minimising potential systemic absorption. Where clinicians believe that an individual child's adherence to the press-and-breathe pMDI and spacer combination is likely to be so poor as to undermine effective asthma control, other alternative devices (taking account of the factors outlined in section 1 above and evidence of equivalence of clinical effectiveness) should be considered, bearing in mind the need to minimise the risks of systemic absorption of corticosteroids.
  - In the case of other inhaled drugs, primarily bronchodilators, it is recommended that a wider range of devices be considered to take account of their more frequent spontaneous use, the greater need for portability, and the clear feedback that symptom response provides to the device user. In such circumstances the factors outlined in section 1 above are likely to be of greater importance in choosing a device.
3. Where more than one device satisfies the considerations outlined above in a particular child, it is recommended that the device with the lowest overall cost (taking into account daily required dose and product price per dose) should be chosen.
4. On selection of an inhaler device, it is important that consideration is given to other aspects of asthma care that influence the effective delivery of inhaled therapy, including:
  - Individual practical training in the use of the specific device
  - Monitoring of effective inhaler technique and adherence to therapy
  - Regular (i.e., no less than annual) review of inhaler needs, which may change over time with increasing age

#### **CLINICAL ALGORITHM(S)**

None provided

### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence supporting the recommendations is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Appropriate selection of inhaler devices for routine treatment of chronic asthma in older children (aged 5-15 years)
- Optimal asthma control

### POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

- National Health Service (NHS) organisations and clinicians (including primary care teams, accident and emergency staff, and specialist paediatric and respiratory staff) should review local practice and policies regarding the prescription of inhaler devices for children between the ages of 5 and 15 with chronic asthma to take account of the guidance (see the "Major Recommendations" field).
- Where local guidelines or care pathways for the care of older children with asthma exist, they should incorporate the guidance (see the "Major Recommendations" field).
- Arrangements should be made to ensure that clinical staff (i.e., doctors and nurses) involved in the prescribing, supply, and administration of inhaler devices to children:
  - Receive suitable education and training in the role of inhaler devices in the treatment of childhood asthma
  - Give sufficient explanation of the full range of inhaler devices available and offer these to children who need them
  - Give effective training in the proper use of devices selected
- To audit local compliance with the guidance (see the "Major Recommendations" field), the following criteria can be used:
  - For a child aged 5 to 15 years being prescribed an inhaler device for asthma for the first time:
    - The child's therapeutic needs and personal needs and preferences are considered when selecting an inhaler device.

- When inhaled corticosteroids are prescribed, a press and breathe pressurized metered dose inhaler (pMDI) and a suitable spacer device are prescribed, consistent with the doctor's assessment of the child's actual or likely adherence to the therapy.
- The child and the child's parent(s) or carer(s) receive effective training in the use of the inhaler device selected.
- If more than one device is appropriate for a child, the least costly device is selected.
- For a child aged 5 to 15 years who has already been prescribed an inhaler device:
  - The child's adherence to therapy and inhaler technique is monitored on an ongoing basis.
  - The child's inhaler-related needs are reviewed at least annually to ensure that the device prescribed continues to meet the child's needs.

See Appendix D of the original guideline document for technical detail on the use of the criteria for audit purposes.

- Local clinical audits on the care of older children with chronic asthma could also include consideration of the measures identified for audit by the British Thoracic Society guidelines.
- Primary care teams also may wish to consider monitoring their prescribing of inhaler types in comparison with other primary care teams.

## **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators  
 Foreign Language Translations  
 Patient Resources  
 Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
 Living with Illness

### **IOM DOMAIN**

Effectiveness  
 Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Inhaler devices for routine treatment of chronic asthma in older children (aged 5-15 years). London (UK): National Institute for Clinical Excellence (NICE); 2002 Mar. 19 p. (Technology appraisal guidance; no. 38).

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2002 Mar (reviewed 2005)

### GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

### SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

### GUIDELINE COMMITTEE

Appraisal Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Committee Members:* Dr Jane Adam, Radiologist, St George's Hospital, London; Dr Sunil Angris, General Practitioner, Waterhouses Medical Practice; Professor David Barnett (*Chair*) Professor of Clinical Pharmacology, University of Leicester; Professor Carol Black, Consultant Physician, Royal Free Hospital & UCL, London; Professor John Brazier, Health Economist, University of Sheffield; Professor Bruce Campbell, Consultant Surgeon, Royal Devon & Exeter Hospital; Professor Mike Campbell, Statistician, Institute of General Practice & Primary Care, Sheffield; Dr Karl Claxton, Health Economist, University of York; Professor Jack Dowie, Health Economist, London School of Hygiene & Tropical Medicine, London; Dr Paul Ewings, Statistician, Taunton & Somerset NHS Trust; Sally Gooch, Director of Nursing, Mid-Essex Hospital Services Trust; Liz Heyer, Chief Executive, Barnet & Chase Farm Hospitals NHS Trust; Ruth Lesirge, Patient Representative; Director, Mental Health Foundation; Dr George Levvy, Patient Representative; Chief Executive, Motor Neurone Disease Association; Dr Gill Morgan, CEO, North & East Devon Health Authority; Professor Miranda Mugford, Health Economist, University of East Anglia; Siân Richards, General Manager, Cardiff Local Health Group; Professor Philip Routledge, Professor of Clinical Pharmacology, University of Wales College of Medicine; Dr Rhiannon Rowsell, Pharmaceutical Physician, AstraZeneca

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## **GUIDELINE STATUS**

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Inhaler devices for routine treatment of chronic asthma in older children (aged 5–15 years). Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Mar. 2 p. (Technology appraisal 38). Available in English and Welsh in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Clinical and cost effectiveness of inhaler devices used in the routine management of chronic asthma in older children. Assessment report. NHS R&D HTA Programme; 2001 Aug. 159 p. Available in Portable Document Format (PDF) from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0048. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria are available in Appendix D of the [original guideline document](#).

## **PATIENT RESOURCES**

The following is available:

- Inhaler devices for routine treatment of chronic asthma in older children (aged 5-15 years). London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Mar. 8 p. (Technology appraisal 38).

Electronic copies: Available in English and Welsh in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](http://www.nice.org.uk).

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N0050. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## **NGC STATUS**

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